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Zacks Small-Cap Research

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David Bautz, PhD
dbautz@zacks.com
(312) 265-9471

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Viking Therapeutics (VKTX-NASDAQ)

VKTX: Positive Results for MGL-3196 Increases Our Confidence for Success of VK2809 Phase 2 Trial…

Based on our probability adjusted DCF model that takes into account potential future revenues of VK5211, VK2809, and VK0214, VKTX is valued at $13/share. This model is highly dependent upon continued clinical success of those compounds and will be adjusted accordingly based upon future clinical results.

Current Price (01/24/18)	$4.72
Valuation	**$13.00**

OUTLOOK

Viking Therapeutics, Inc. (VKTX) is currently testing VK2809, the company's lead thyroid hormone receptor beta (TRβ) agonist, in a Phase 2 clinical trial in patients with hypercholesterolemia and fatty liver disease. Madrigal Pharmaceuticals (MDGL) recently announced positive results from an ongoing Phase 2 study of its lead TRβ agonist, MGL-3196, in patients with NASH. We view this as a positive read-through for Viking given the very similar mechanism of action between the two drugs. In addition, we view any fears surrounding potential increases in liver enzymes caused by VK2809 as likely overstated and potentially related to how adverse events were defined in the Phase 1 trial (which was conducted by Metabasis Therapeutics, Inc.). We are increasing our valuation to $13 per share.

SUMMARY DATA

52-Week High	**$5.12**
52-Week Low	**$0.93**
One-Year Return (%)	**227.78**
Beta	**1.88**
Average Daily Volume (sh)	**685,418**
Shares Outstanding (mil)	**36**
Market Capitalization ($mil)	**$169**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
Insider Ownership (%)	**20**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-7.0**
P/E using 2019 Estimate	**-7.4**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	0 A	0 A	0 A	0 A	0 A
2017	0 A	0 A	0 A	0 E	0 E
2018					0 E
2019					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.40 A	- $0.22 A	-$0.20 A	-$0.18 A	-$0.90 A
2017	-$0.23 A	-$0.21 A	-$0.22 A	-$0.19 E	-$0.85 E
2018					-$0.72 E
2019					-$0.70 E

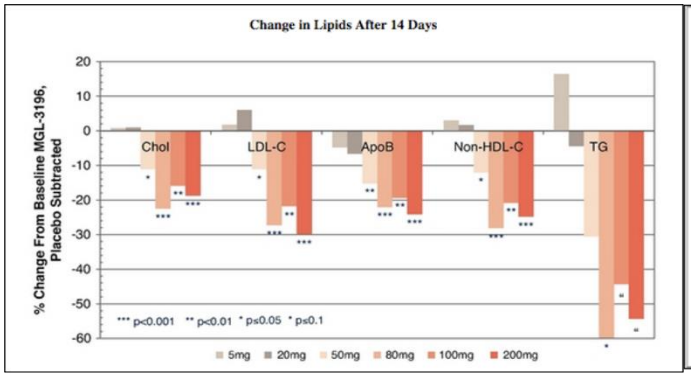
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WHAT'S NEW

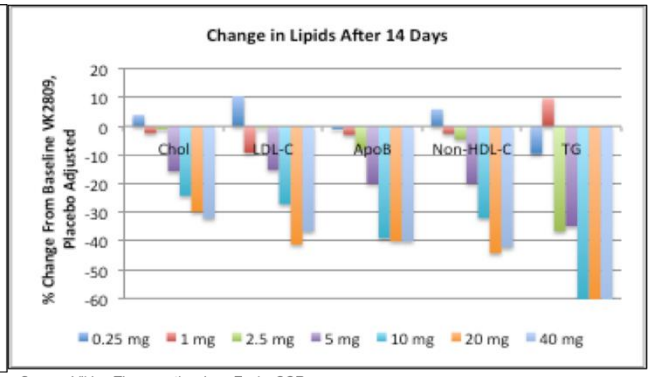
Business Update

Viking Therapeutics, Inc. (VKTX) is currently testing VK2809, the company's thyroid hormone receptor beta (TRβ) agonist, in a Phase 2 clinical trial in patients with hypercholesterolemia and fatty liver disease. The company is enrolling patients with elevated cholesterol and fatty liver disease, as assessed by liver fat content ≥ 8% by MRI-PDFF. The primary endpoint will assess changes in LDL cholesterol following 12 weeks of treatment, with exploratory endpoints evaluating changes in liver fat content, inflammatory markers, and histological changes. We anticipate topline results in the first half of 2018.

Madrigal Pharmaceuticals, Inc. (MDGL) is currently testing MGL-3196, also a TRβ agonist, in a Phase 2 study of 125 patients with liver biopsy-confirmed NASH. Since it is also a TRβ agonist, we think that VK2809 is likely to show similar results to MGL-3196, particularly since both compounds show very similar activity in reducing lipid profiles, as can be seen by comparing the following two graphs:



Source: Madrigal Pharmaceuticals, Inc.



Source: Viking Therapeutics, Inc.; Zacks SCR

The primary endpoint of the MGL-3196 Phase 2 study is reduction of liver fat at 12 weeks compared to baseline, assessed by MRI-PDFF, with efficacy confirmed at the end of the trial (36 weeks). We anticipate 36-week results in the second quarter of 2018. Madrigal announced 12-week results on Dec. 6. 2017, which showed statistically significant results for the primary endpoint and statistically significantly more MGL-3196 treated patients achieved at least a 30% reduction in liver fat at 12 weeks. The results are shown in the tables below.

	ALL MGL-3196	HIGH MGL-3196**	Placebo
Numbers of patients	78	44	38
Relative change in MRI-PDFF (% change from baseline, median)	-36.3%	-42.0%	-9.6%
Significance relative to placebo	p<0.0001	p<0.0001	
Percentage of patients attaining ≥30% liver fat reduction	60.3%	75.0%	18.4%
Significance relative to placebo	p<0.0001	p<0.0001	

**Prespecified group of patients (44/78) with relatively higher MGL-3196 drug levels

Source: Madrigal Pharmaceuticals, Inc.

The data are impressive, particularly when compared to the changes in liver fat seen with other compounds currently in development. We note that it is difficult to make an "apples to apples" comparison across different clinical trials, however we believe it is a useful exercise in putting data into context. As an example, in October 2017, Gilead announced results from a Phase 2 study of GS-0976 in patients with NASH that showed the change in liver fat and the percentage of patients attaining ≥30% reduction in liver fat to be far below that seen with MGL-3196, as shown in the table below.

Relative (%) Changes in Imaging, ALT and Serum Fibrosis Markers at Week 12*

Endpoint (Week 12)	GS-0976 20 mg (n=49)	GS-0976 5 mg (n=51)	Placebo (n=26)	P-values 20 mg vs. Placebo	P-values 5 mg vs. Placebo
MRI-PDFF	-28.9	-13.0	-8.4	**0.002**	0.142
≥30% reduction in MRI-PDFF, % (n/N)	48% (22/46)	23% (11/47)	15% (4/26)	**0.004**	0.433
MRE-stiffness	-5.5	-9.6	-12.5	0.100	0.743
Liver stiffness by FibroScan	-11.1	-8.4	-3.1	0.212	0.364
ALT	-20.5	-9.8	-6.7	0.176	0.765
TIMP-1	-7.9	-2.9	-1.5	**0.022**	0.301
PIII-NP	-13.9	-7.0	-0.5	0.107	0.605

Source: Gilead Sciences, Inc.

Liver fat reduction is an important outcome in NASH, as it could be associated with improvement in liver histology. A secondary longitudinal analysis of the MOZART trial (which tested ezetimibe in biopsy-proven NASH patients) showed that "responders" (defined as patients with a ≥2 point reduction in the NAFLD Activity Score, NAS) had a mean 29.3% decrease in liver fat compared to "non-responders" that had a 2.0% increase in liver fat (Patel *et al*., 2016). Thus, compounds that decrease liver fat could lead to improvements in NASH, and we anticipate treatment with VK2809 leading to similar reductions in liver fat to MGL-3196.

No Liver Toxicity Issues for VK2809

We have heard from a number of investors regarding concern about potential adverse liver effects of VK2809 based on treatment related adverse events reported in the Phase 1 clinical trial. We believe these concerns may be overstated and could be related to how adverse events were defined for that trial, which was conducted by Metabasis Therapeutics, Inc. (later acquired by Ligand Pharmaceuticals). The following chart from a poster presented in 2016 shows treatment-related adverse events from that study.

Treatment-Emergent, Treatment-Related AEs in 2 or more VK2809-Treated Subjects in VK2809-102 (# of subjects)

	VK2809 DOSE GROUP (mg)							
	Placebo	**0.25**	**1**	**2.5**	**5**	**10**	**20**	**40**
Number of Subjects Dosed	**14**	**6**	**6**	**6**	**6**	**6**	**6**	**6**
ADVERSE EVENT								
Gastrointestinal Disorders								
Abdominal discomfort	0	0	0	0	0	0	1	1
General Disorders and Administration Site								
Fatigue	0	0	0	1	0	1	1	0
Investigations								
Alanine aminotransferase increased	0	0	1	1	1	1	3	3
Aspartate aminotransferase	0	0	0	0	0	1	1	2
Blood bilirubin increased	0	0	0	0	0	0	1	1
Blood bilirubin unconjugated	0	0	0	0	0	0	1	1
Urine colour abnormal	0	0	0	0	0	2	0	0
Nervous System Disorders								
Dizziness	0	0	0	1	0	0	0	1
Headache	4	0	0	1	0	1	2	2
Psychiatric disorders								
Insomnia	1	0	0	3	0	1	2	1

Data excerpted from Appendix 16.2.7.2

Source: Lian *et al*., 2016

Three out of six subjects were reported to have increased alanine aminotransferase (ALT) levels at both the 20 mg and 40 mg dose levels. We believe this table is one of the central reasons for the discussion around the liver safety of VK2809. However, it's important that investors realize that, in this study, ALT-related adverse events were defined as an increase from baseline by some undisclosed margin. This is notable because, typically, such increases are reported when they reach a certain multiple above the upper limit of normal (ULN). For ALT in particular, many studies simply report the number of patients experiencing an elevation that is 3X or 5X ULN. This study's unfortunate characterization approach has, in our view, led to much speculation as to the safety of VK2809.

As an example, consider a patient who demonstrated a baseline ALT of 15 U/L. If this patient's ALT increased to 45 U/L, he/she would likely have been considered an AE in this study, even in the absence of clinical signs or symptoms. However, under the more traditional method, this patient's ALT level might actually be considered to be within normal limits (depending on the lab where the test was performed). This level of ALT elevation would almost certainly not merit an AE label under the multiple of ULN approach.

In this context, it's illustrative to revisit the table above using the more traditional 3X ULN characterization. Under that approach, the adverse event table would look more like the following.

	VK2809 Dose Group							
	Placebo	0.25 mg	1 mg	2 mg	5 mg	10 mg	20 mg	40 mg
Number of Subjects Dosed	14	6	6	6	6	6	6	6
No. (%) of subjects with value >3X ULN at any time point								
ALT	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (17)
AST	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (17)
No. (%) of subjects with total bilirubin >2X ULN at any time point	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Source: Zacks SCR

As shown, in the 40 mg group in this study there was one reported case of ALT or AST >3x ULN. From the 2016 poster, we also know that the highest mean ALT levels in this study reached 1.5X the ULN (40 mg group). In the 40 mg patient from the table, Viking has stated that dosing was continued uninterrupted. Interestingly, despite the continued dosing the patient's ALT returned to normal by the end of the 14-day study.

In our view, this table and analysis paints a different picture of liver-related adverse events for VK2809, which is better aligned with typical reporting metrics and potentially less unsettling to investors. We don't see liver toxicity as an issue for VK2809 based on the above data, particularly since Viking is using 5 and 10 mg doses in the Phase 2 study.

Financial Update

On December 11, 2017, Viking announced the closing of an underwritten public offering of 5.9 million shares of common stock, including 769,565 shares sold pursuant to the underwriter's over-allotment, at $2.50 per share, resulting in gross proceeds to Viking of approximately $14.8 million. We estimate Viking exited 2017 with approximately $20 million in cash and cash equivalents and as of Dec. 31, 2017 the company had 35.8 million shares outstanding.

Conclusion

Based on the performance of Madrigal's stock over the past couple of months it appears investors think decreasing liver fat is an important outcome for patients with NASH, which we agree with. What we don't understand is the widening valuation gap between Madrigal and Viking given the same mechanism of action for MGL-3196 and VK2809 along with the very similar results for those two compounds in decreasing lipid levels. While we are unsure whether the discrepancy in valuation between the two companies is due to investor's fears of potential liver toxicity issues regarding VK2809, we are hopeful the preceding will help to shed light on the subject and give everyone a more informed view of the issue. We see the results for MGL-3196 as a positive read-through for VK2809 and we are increasing our valuation to $13 per share, and believe investors should take a serious look at Viking ahead of the Phase 2 results for VK2809 in the second quarter of 2018.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2016 A	Q1 A	Q2 A	Q3 A	Q4 E	2017 E	2018 E	2019 E
VK5211 (Hip Fracture)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
VK2809 (Hypercholesterolemia)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
VK0214 (ALD)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$9.0	$3.5	$3.7	$3.5	$3.8	$14.5	$16.0	$18.0
General & Administrative	$4.8	$1.4	$1.3	$1.2	$1.3	$5.2	$5.7	$6.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($13.8)	($5.0)	($5.0)	($4.7)	($5.1)	($19.7)	($21.7)	($24.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.9)	($0.3)	($0.2)	($1.4)	($0.1)	($1.9)	($0.5)	($0.6)
Pre-Tax Income	($14.7)	($5.22)	($5.17)	($6.1)	($5.2)	($21.7)	($22.2)	($24.6)
Income Taxes Paid	($0)	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($14.7)**	**($5.2)**	**($5.2)**	**($6.1)**	**($5.2)**	**($21.7)**	**($22.2)**	**($24.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.90)**	**($0.23)**	**($0.21)**	**($0.22)**	**($0.19)**	**($0.85)**	**($0.72)**	**($0.70)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	16.278	22.353	24.119	27.470	28.000	25.485	31.000	35.000

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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